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| 10/008,778      | 11/13/2001  | Eric Hauser Kuhrts   | 68911-076           | 4731             |

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| EXAMINER |
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MELLER, MICHAEL V

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1655

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08/27/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/008,778 | <b>Applicant(s)</b><br>KUHRTS, ERIC HAUSER |  |
|                              | <b>Examiner</b><br>Michael V. Meller | <b>Art Unit</b><br>1655                    |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14, 16 and 18-27 is/are pending in the application.
- 4a) Of the above claim(s) 1-12, 14, 16 and 18-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

The restriction requirement of record is maintained for the reasons of record. Claims 1-12, 14, 16, 18-27 are withdrawn from further consideration since they are drawn to non-elected subject matter. The restriction requirement has already been made **FINAL** as noted by applicants.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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2. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rigby et al. (US 3354219) in view of Todd, Jr. et al. (US 5041300) and as evidenced by Medicinenet.com and About.com.

3. Rigby teaches that hot water, NaOH, and hops are boiled for two hours, see col. 4, lines 5-70. The reference also notes that KOH (potassium hydroxide) can be used instead of NaOH. It is noted that the composition has a milder odor and flavour thus someone drank the composition. Medicine net makes it clear that acute pain comes on quickly thus it reads on anyone since anyone can have acute pain. About.com makes it clear that standardized extracts have been processed to contain a specific amount of a compound but as see in Rigby once the extract is reacted with the KOH a specific amount of iso-alpha acids are formed, namely 2.4 g of isohumulones, see col. 4, lines 15-25.

4. Rigby does not teach the claimed amount of COX-2 inhibitor.

5. Todd teaches that 50 ppm of isoalpha acids were added to beer, see col. 13, lines 25-40.

In the event that using the KOH instead of NaOH is seen as obviousness instead of anticipation, (which this examiner highly doubts) it still would be obvious to one having ordinary skill in the art to use the KOH instead of the NaOH since Ribgy clearly indicates that "obvious commercial alternatives are possible" and then goes on to list KOH as one of the options. Clearly the KOH was envisioned to be used instead of the NaOH.

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Further it would have been obvious to use the claimed amount of COX-2 inhibitor since Todd makes it clear that 50 ppm of isoalpha acids were added to beer to yield beneficial results, see col. 13, lines 25-40 of Todd. This translates to 50 mg/liter which clearly would provide motivation for one of ordinary skill in the art to use the iso alpha acids of Rigby at a concentration of 5 mg to 1,000 mg per day since in Rigby one is consuming beer as they are in Todd and 3 beers would be equivalent to one liter which would equate to 50 mg. One beer would equate to 17.75 mg which is well within the claimed range as well. Thus, the claimed invention is obvious.

Applicant argues that Rigby does not teach that the claimed composition can treat the claimed conditions. It was established on the record already that anyone suffers from acute pain for the reasons of record, thus the claimed invention reads on administration to anyone thus the claims are met by Rigby. Applicant then argues that the amount of the composition was not taught but this was taught by Todd for the reasons of record.

Medicine.net was stated as only providing a definition of acute pain but this states and establishes that acute pain reads on anyone, not any particular patient population, we all have pain.

Applicant then argues that Todd does not teach treatment of the claimed conditions, but as stated above, the claimed condition, acute pain, is suffered by anyone.

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Applicant argues that claim 13 allegedly does not read on Todd's beer because the claim is related to a composition "consisting essentially of" a COX-2 inhibitor and beer is allegedly not known to be a pharmaceutical COX-2 inhibitor let alone having a COX-2/COX-1 ratio of 0.23 to 3.33. This is noted but "consisting essentially of" still reads on the claimed composition since Rigby teaches isohumulones which are clearly what is being administered and are clearly COX-2 inhibitors. Note that Rigby and Todd both teach beer, see the noted places already of record. Thus, a beer will inherently have the claimed "consisting essentially of" a COX-2 inhibitor as claimed for the reasons of record.

### ***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claim 13 is provisionally rejected on the ground of nonstatutory double patenting over claims 8-10, 13-15 of copending Application No.11409521. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the claims of the application (11409521) claim a condition which can read on acute pain and as disclosed rheumatoid arthritis and osteoarthritis.

8. Claim 13 is rejected on the ground of nonstatutory double patenting over claims 1-7, 9-23 of U. S. Patent No. 7279186 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: the patent claims treating inflammation and as defined in the specification of the patent includes osteoarthritis, acute pain and rheumatoid arthritis.

Applicant argues that the patent and the application were both filed after the filing date of the instant case, but unless the obviousness type double patenting rejections are the only remaining rejections in the instant case, the rejections will remain.

**If applicant is aware of any other applications/patents which would constitute an Obviousness type double patenting rejection (such as the ones above), applicant is required to put such evidence on the record and submit terminal disclaimers to obviate those applications/patent as well as the above listed ones.**

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael V. Meller/  
Primary Examiner, Art Unit 1655